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PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/645,863	
	Filing Date	August 20, 2003	
	First Named Inventor	Jonathan C. HELLER et al.	
	Art Unit	2855	
	Examiner Name	Unassigned	
Total Number of Pages in This Submission		Attorney Docket Number	29191-707

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Itemized return postcard
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<input checked="" type="checkbox"/> Information Disclosure Statement	<input checked="" type="checkbox"/> CD, Number of CD(s) 1	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<b>Remarks</b>	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

**SIGNATURE OF APPLICANT, ATTORNEY OR AGENT**

Firm or Individual name	U.P. Peter Eng, Reg. No. 39,666, WILSON SONSINI GOODRICH & ROSATI		
Signature			
Date	7/8/04		

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as Express mail (Label No. EV333489783US) in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>July 9, 2004</u>			
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT

Attorney Docket No. 29191-707

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Jonathan C. HELLER et al.	)	
	)	Art Unit: 2855
Application No.: 10/645,863	)	
	)	Examiner: Unassigned
Filed: August 20, 2003	)	
	)	
Title: System of Analyzing Complete Mixtures of	)	
Biological and Other Fluids to Identify	)	
<u>Biological State Information</u>	)	

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - ☒ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; **or**
  - ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☒ Copies of each of the references listed on the attached Forms PTO-1449 are enclosed herewith. Due to the voluminous nature of the references, each reference is provided in PDF format on the attached CD ROM, clearly titled by publication number or author.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. ), copies are not enclosed herewith.
  - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29191-707).

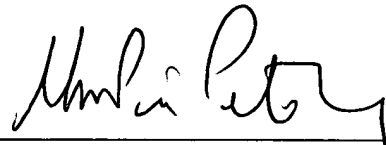
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: \_\_\_\_\_

7/8/04

By: \_\_\_\_\_



U.P. Peter Eng, Reg. No. 39,666

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/645,863
				Filing Date	August 20, 2003
				First Named Inventor	Jonathan C. HELLER et al.
				Art Unit	2855
				Examiner Name	Unassigned
Sheet	1	of	6	Attorney Docket Number	29191-707

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-5,227,471	07-13-1993	Wright, Jr.	
		US-5,314,996	05-24-1994	Wright, Jr.	
		US-5,639,656	06-17-1997	Wright, Jr.	
		US-6,157,921	12-05-2000	Barnhill	
		US-6,207,370-B1	03-27-2001	Little et al.	
		US-6,306,087-B1	10-23-2001	Barnhill et al.	
		US-6,309,816-B1	10-30-2001	Zhang et al.	
		US-6,363,383-B1	03-26-2002	Kindo et al.	
		US-6,427,141-B1	07-30-2002	Barnhill	
		US-6,558,955-B1	05-06-2003	Kristal et al.	
		US-6,658,395-B1	12-02-2003	Barnhill	
		US-6,675,104-B1	01-06-2004	Paulse et al.	
		US-6,714,925-B1	03-30-2004	Barnhill et al.	
		US-2002/0095260-A1	07-18-2002	Huyn	
		US-2002/0138208-A1	09-26-2002	Paulse et al.	
		US-2002/0193950-A1	12-19-2002	Gavin et al.	
		US-2003/0004402-A1	01-02-2003	Hitt et al.	
		US-2003/0013120-A1	01-16-2003	Patz, Jr. et al.	
		US-2003/0077611-A1	04-24-2003	Slepnev	
		US-2003/0132114-A1	07-17-2003	Mischak et al.	
		US-2003/0134304-A1	07-17-2003	van der Greef et al.	
		US-2003/0148295-A1	08-07-2003	Wan et al.	
		US-2003/0148922-A1	08-07-2003	Knapp et al.	
		US-2003/0153007-A1	08-14-2003	Chen et al.	
		US-2003/0228639-A1	12-11-2003	Wright et al.	
		US-2004/0005634-A1	01-08-2004	Patz, Jr. et al.	
		US-2004/0018519-A1	01-29-2004	Wright, Jr.	
		US-2004/0029194-A1	02-12-2004	Parish et al.	
		US-2004/0043436-A1	03-04-2004	Vlahou et al.	
Examiner Signature				Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	6	Attorney Docket Number	29191-707

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>2</sup> - Kind Code <sup>2</sup> (if known)				
		WO-95/25281-A1	09-21-1995	Univ. of Washington		
		WO-01/25791-A2	04-12-2001	Ciphergen Biosystems, Inc.		
		WO-01/36977-A2	05-25-2001	Matritech, Inc.		
		WO-01/57263-A1	08-09-2001	Advion Biosciences, Inc.		
		WO-01/57518-A2	08-09-2001	Yolbolsum Canada Inc.		
		WO-01/71360-A2	09-27-2001	Eastern Virginia Medical School		
		WO-02/04957-A2	01-17-2002	Esperion Therapeutics, Inc.		
		WO-02/08760-A1	01-31-2002	Biotron Limited		
		WO-02/97703-A2	12-05-2002	Emili, Andrew et al.		
		WO-02/27329-A2	04-04-2002	Eastern Virginia Medical School		
		WO-02/46448-A2	06-13-2002	Eastern Virginia Medical School		
		WO-03/14302-A2	02-20-2003	MDS Proteomics, Inc.		
		WO-03/31031-A1	04-14-2003	Ciphergen Biosystems, Inc. et al.		
		WO-03/38055-A2	05-08-2003	MDS Proteomics, Inc.		
		WO-03/42774-A2	05-22-2003	Caprion Pharmaceuticals, Inc.		
		WO-03/72710-A2	09-04-2003	Eastern Virginia Medical School		
		WO-03/83442-A2	10-09-2003	Perlegen Sciences, Inc.		
		WO-03/91695-A2	11-06-2003	Johns Hopkins Univ.		
		WO-03/97799-A2	11-27-2003	Eastern Virginia Medical School		
Examiner signature				Date Considered		

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<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
		ADKINS, Joshua N., et al., "Toward a human blood serum proteome: analysis by multidimensional separation coupled with mass spectrometry". The American Society for Biochemistry and Molecular Biology, Inc., MCP Paper (November 15, 2002)			
		ANDERSON, Leigh, et al., "A comparison of selected mRNA and protein abundances in human liver". Electrophoresis (1997), 18:533-537.			
		ANDERSON, N. Leigh, et al., "The Human Plasma Proteome". Molecular & Cellular Proteomics (2002), 1:845-867.			
		BANEZ, Lionel L., et al., "Diagnostic potential of serum proteomic patterns in prostate cancer". The Journal of Urology (2003) 170:442-446.			
		BILLINGSLEY, Janice, "Research offers hope in fight against ovarian cancer". Health & Science (Feb 8, 2002) 3 pages.			
		CAO, Ping et al., "Analysis of peptides, proteins, protein digests, and whole human blood by capillary electrophoresis/electrospray ionization-mass spectrometry using an in-capillary electrode sheathless interface". J Am Soc Mass Spectrometry (1998), 9:1081-1088.			
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		/			
		CRISP - Computer retrieval of information on scientific projects [abstract], << <a href="http://commons.clt.nih.gov/crisp3/CRISP_LIB.getdoc?textkey=6388327&amp;p_grant_num=5R01HG002033-03&amp;p_query=&amp;ticket=...&gt;&gt;">http://commons.clt.nih.gov/crisp3/CRISP_LIB.getdoc?textkey=6388327&amp;p_grant_num=5R01HG002033-03&amp;p_query=&amp;ticket=...</a> >>. Downloaded May 9, 2002, 2 pages.			
		DIAMANDIS, Eleftherios P., "Point proteomic patterns in biological fluids: do they represent the future of cancer diagnostics?". Clinical Chemistry (2003) 49(8)1272-1278.			
		EDITORIAL, "Proteomic diagnostics tested". Nature (June 3, 2004), 429(3)487.			
		ETZIONI, Ruth, et al., "Combining biomarkers to detect disease with application to prostate cancer". Biostatistics (2003), 4(4)523-538.			
		ETZIONI, Ruth, et al., "The case for early detection". Nature Reviews/Cancer (April 2003), 3:1-10.			
		GERACIMOS, A., "Outwitting Ovarian Cancer". Correlogic Systems, Inc., Press Release dated April 16, 2002, 4 pages.			
Examiner signature				Date Considered	

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				Art Unit	2855
				Examiner Name	Unassigned
Sheet	4	of	6	Attorney Docket Number	29191-707
<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
		GYGI, Steven P., "Correlation between protein and mRNA abundance in yeast". Molecular and Cellular Biology (March 1999) 1720-1730.			
		HARAN, Christine, "The promise of proteins - Do these tricky molecules hold the answers to cancer?". (October 2---) 43-46.			
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		HENRY, Celia, "Diagnosing ovarian cancer - Proteomics shows promise of early detection of deadly disease". Science (Feb 18, 2003) 18.			
		HILARIO, Melanie, et al., "Machine learning approaches to lung cancer prediction from mass spectra". Proteomics (2003) 3:1716-1719.			
		HOLLON, Tom "Software Zeroes in on ovarian cancer". The Scientist (April 15, 2002) 16(8):16.			
		JOHANNES, Laura, "Tiny protein may lead to better screen test for prostate cancer". Dow Jones (Nov. 4, 2003), 1-2.			
		LEHRER, S., et al., "Putative protein markers in the sera of men with prostatic neoplasms". BJU International (2003) 92:223-225.			
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		LIOTTA, Lance A. et al., "Written in blood", Nature (10/30/2003), 425:905.			
		MARKEY, Mia K., et al. "Decision tree classification of proteins identified by mass spectrometry of blood serum samples from people with and without lung cancer". Proteomics (2003) 3:1678-1679.			
		MARSHALL, John, et al., "Processing of serum proteins underlies the mass spectral fingerprinting of myocardial infarction". Journal of Proteome Research (January 20, 2003) 12 pages.			
		MIAN, Shahid, et al., "A prototype methodology combining surface-enhanced laser desorption/ionization protein chip technology and artificial neural network algorithms to predict the chemoresponsiveness of breast cancer cell lines exposed to Paclitaxel and Doxorubicin under in vitro conditions". Proteomics (2003) 3:1725-1737.			
		MILLER, Jeremy C., et al., "Antibody microarray profiling of human prostate cancer sera: Antibody screening and identification of potential biomarkers". Proteomics (2003) 3:56-63.			
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Attorney Docket No. 29191-707



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		NEVILLE, Padraic, et al., "Generalizable mass spectrometry mining used to identify disease state biomarkers from blood serum". Proteomics (2003) 3:1710-1715.			
		PUROHIT, Parul V., et al., "Discriminant models for high-throughput proteomics mass spectrometer data". Proteomics (2003) 3:1699-1703.			
		QU, Yinsheng, et al., "Boosted decision tree analysis of surface-enhanced laser desorption/ionization mass spectral serum profiles discriminates prostate cancer from noncancer patients". Clinical Chemistry (2002), 48(10):1835-1843.			
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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/645,863
				Filing Date	August 20, 2003
				First Named Inventor	Jonathan C. HELLER et al.
				Art Unit	2855
				Examiner Name	Unassigned
Sheet	6	of	6	Attorney Docket Number	29191-707
<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
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